



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Tsunehiro FUKUCHI et al.:

Serial No. 10/522,603:

Art Unit: 1655

Filed: January 26, 2005:

Examiner: Catheryne CHEN

5 For: CHINESE HERBAL MEDICAL COMPOSITION IN THE FORM OF  
JELLY

**DECLARATION**

Honorable Commissioner for Patents

Sir:

10 I, Tsunehiro FUKUCHI, a citizen of Japan residing in A201, East  
16, 541, Kirai, Higashikagawa-shi, Kagawa-ken, Japan, declare as  
follows:

I graduated from Kagawa University, Department of Education in  
1991, and graduated Kyushu Institute of Technology, School of  
15 Computer Science and System Engineering in 1994.

From 1994 to now, I have been employed in TEIKOKU SEIYAKU  
CO., LTD. and I have engaged in research and development on the  
preparation of Chinese medicines in said company.

I am one of inventors of the above patent application (U.S. Serial  
20 No. 10/522,603) and am familiar with subject matter thereof.

Under my supervision the following tests were carried out.

In order to clarify the effect by a combination of carrageenan,  
carob (locust) bean gum and xanthan gum, following experiments were  
25 carried out.

### Preparation of sample

Each ingredient shown in the formula was weighed, and ingredients were homogenously mixed and stirred, followed by addition of water. The mixture was dissolved under stirring at 70 to 80°C for 1 hour. Then after confirming being dissolved, the solution was poured into a stick-like vessel sealed at three parts and was cooled in a refrigerator for 5 hours to prepare a jelly preparation.

### Measurement on syneresis:

The samples preserved at 25°C (60%RH).

The method was carried out by standing on end of a stick-like packed vessel sealed at three parts into which a Chinese herbal medical composition in the form of jelly was poured. The ratio of the weight of syneresis remained in the air portion per total amount was calculated.

### 1) Comparative experiment A

This experiment was carried out on syneresis in case of using  $\kappa$ -carrageenan as a gelling agent in example 2 of JP 4346937 (Comparative Ex.1-1) and in case of using further locust (carob) bean gum and xanthan gum (Comparative Ex.1-2).

Ingredient	Comparative Ex.1-1	Comparative Ex.1-2
Aqueous dry extract of Sho-saiko-to(小柴胡湯)	3.92 (%)	3.92 (%)
<b><math>\kappa</math>-Carrageenan</b> WR-712C	1.19	1.19
<b>Locust bean gum</b>	-	0.19
<b>Xanthan gum</b>	-	0.44
Sugar	16.39	16.39
Purified water	78.50	77.87
Total	100	100

## Result

Syneresis(%) at 25°C 60%RH

Preservation term (day)	Comparative Ex.1-1	Comparative Ex.1-2
0	0.00	0.00
1	1.99	1.20
4	2.47	2.10
12	3.27	2.54

The above results are also shown in Fig. 1 below.

As shown in Fig.1, by using a combination of  $\kappa$ -carrageenan, carob bean gum and xanthan gum, the syneresis was considerably improved comparing with in case of using only  $\kappa$ -carrageenan.

## 2) Comparative experiment B

This experiment was carried out on syneresis in case of using an aqueous dry extract of Kakkon-to (葛根湯) instead of orange juice in Reference example (Table 6) of Ninomiya et al. (US Patent 5,932,235) (Comparative Ex.2-1) and in case of using further xanthan gum (Comparative Ex.2-2). As a control, the preparation of Example 4 of the present specification was used.

Ingredient	Comparative Ex.2-1	Comparative Ex.2-2
Aqueous dry extract of Kakkon-to(葛根湯)	10	10
<b><math>\kappa</math>-Carrageenan</b>	0.4	0.4
<b>Carob bean gum</b>	0.4	0.4
<b>Xanthan gum</b>	-	0.4
Polyacrylic acid sodium	0.01	0.01
Sodium citrate	0.25	0.25
Citric acid	0.05	0.05
White soft sugar	8	8
Methylparaben	0.03	0.03
Purified water	80.86	80.46
Total	100	100

## Result

Syneresis(%) at 25°C 60%RH

Preservation term (day)	Comparative Ex.2-1	Comparative Ex.2-2
0	0.00	0.00
1	4.46	1.14
4	5.59	3.00
12	10.15	5.25

The above results are also shown in Fig. 2 below.

As shown in Fig.2, by using a combination of  $\kappa$ -carrageenan, carob bean gum and xanthan gum (Comparative Ex.2-2), the syneresis was drastically (unexpectedly) improved comparing with in case of using a combination of carrageenan and carob bean gum (Comparative Ex. 2-1).

## 3) Comparative experiment C

This experiment was carried out on syneresis in cases of deletion of xanthan gum (Comparative Ex.3-1), and further carob bean gum (Comparative Ex.3-2) from the composition of Example 4 of the present specification, and the preparation of said Example 4.

Ingredient	Example 4	Comparative Ex. 3-1	Comparative Ex. 3-2
Aqueous dry extract of Kakkon-to(葛根湯)	15	15	15
<b><math>\kappa</math>-Carrageenan</b>	1	1	1
<b>Carob bean gum</b>	0.25	0.25	-
<b>Xanthan gum</b>	0.45	-	-
powdered hydrogenated maltose starch syrup	6	6	6
D-Sorbitol	6	6	6
glycerin	6	6	6
Propylene glycol	1	1	1
Propyl parahydroxybenzoate	0.02	0.02	0.02
Purified water	64.28	64.73	64.98
Total	100	100	100

## Result

Syneresis(%) at 25°C 60%RH

Preservation term (day)	Comparative Ex. 3-1	Comparative Ex. 3-2	Example 4
0	0.00	0.00	0.00
1	1.35	1.47	0.70
4	1.84	2.27	1.58
12	2.79	3.16	2.33

The above results are also shown in Fig.3 below.

As shown in Fig.3 of the Declaration, every time when each  
 5 ingredient is deleted, the rate of syneresis clearly increased.

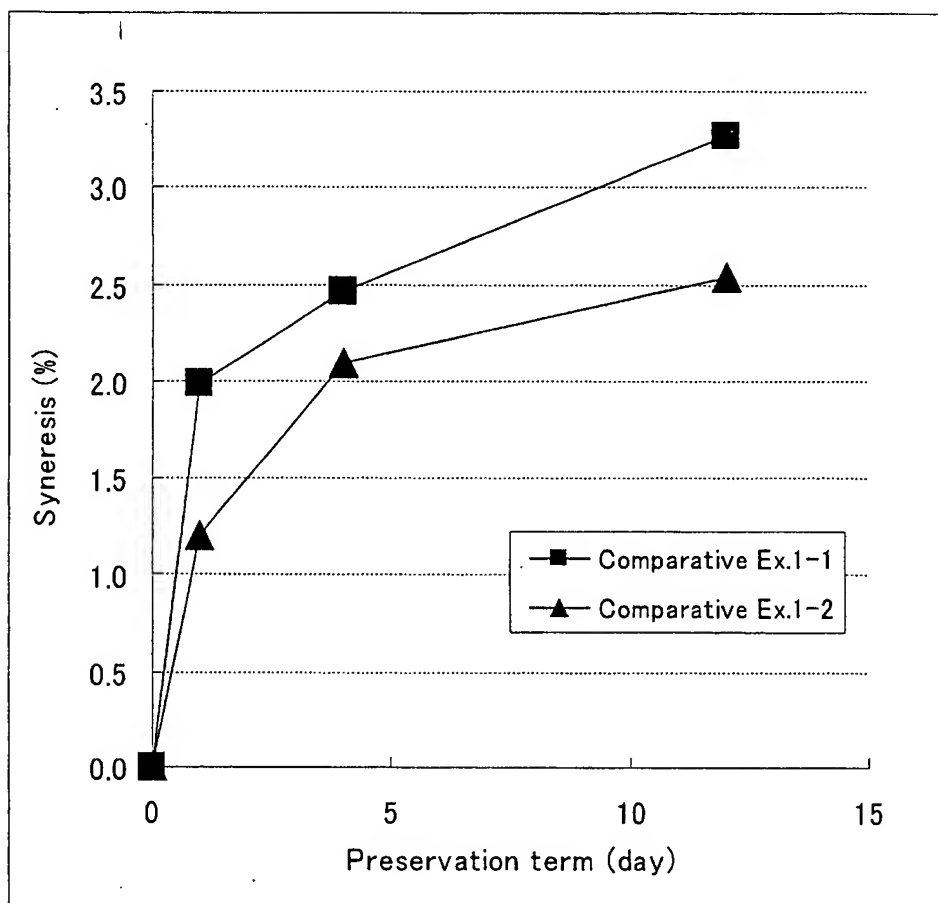


Fig. 1

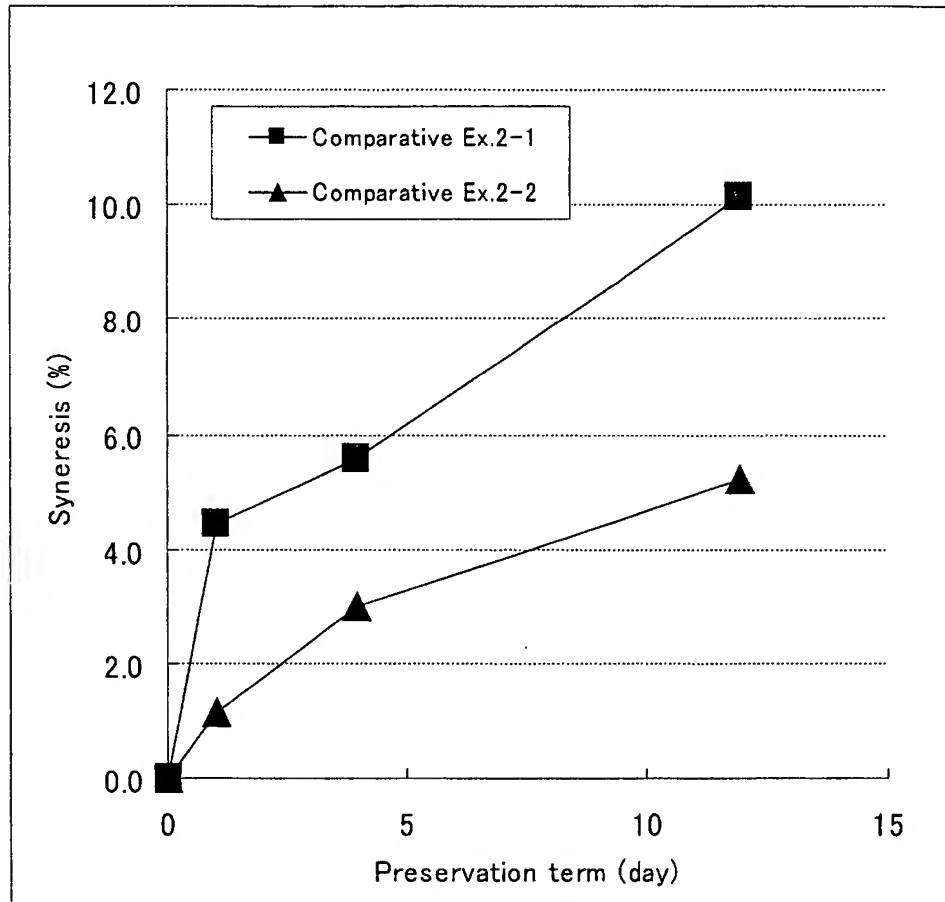


Fig.2

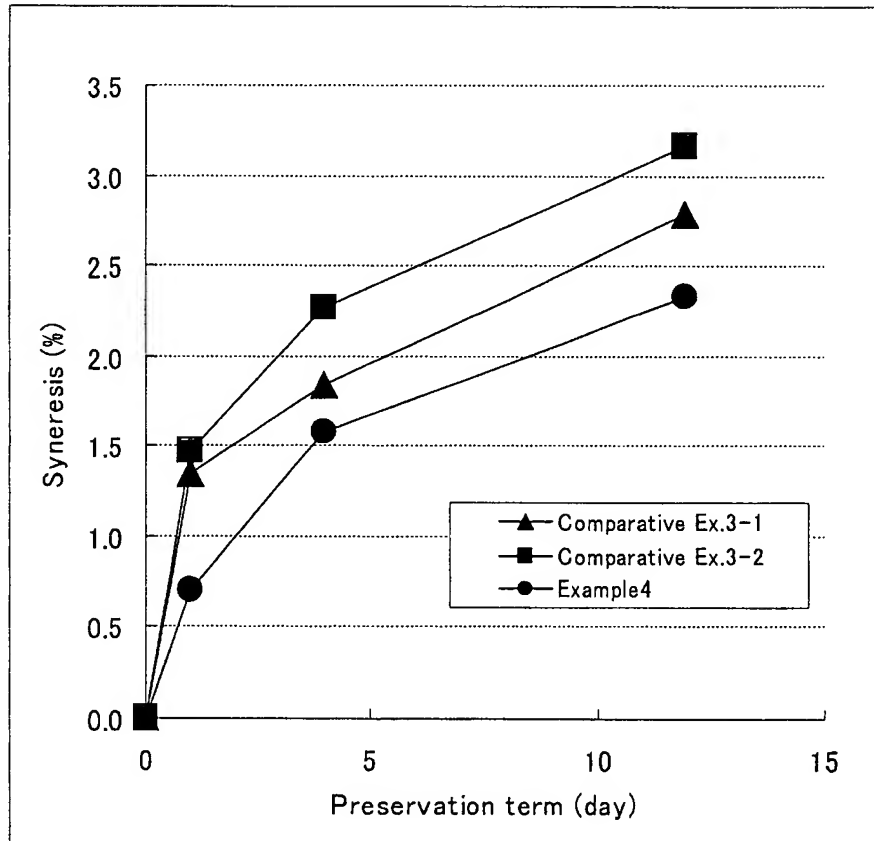


Fig.3

The undersigned declares further that all statements made herein  
of my own knowledge are true and that all statements made on  
information and belief are believed to be true; and further that these  
5 statements were made with the knowledge that willful false statements  
and the like so made are punishable by fine or imprisonment, or both,  
under Section 1001 of Title 18 of the United State Code and that such  
willful false statements may jeopardize the validity of the above-  
10 mentioned application or any patenting thereon.

This 28 of March, 2007

Tsunehiro Fukuchi

Tsunehiro FUKUCHI